DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

M3131

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

September 16, 1999

WARNING LETTER
CHI-32-99

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Harry Jansen Kraemer, Jr.
President & CEO
Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015

Dear Mr. Kraemer:

During an inspection of your establishment located in Round Lake, IL, from May 24, 1999, to June 16, 1999, FDA investigators Chad E. Schmear and Ray L. Walchle, determined that your establishment manufactures infusion pumps. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish adequate corrective and preventive action procedures. For example, your firm's corrective and preventive action procedures failed to define the following:

    - identification of corrective and preventive actions,
    - use of appropriate statistical methodology to identify quality problems,
    - investigation of the cause of nonconformities not identified by a complaint,
    - verification or validation of corrective and preventive actions.

2. Corrective and preventive actions have not been verified or validated to ensure the action is effective and does not adversely effect the device. For example, verification or validation of activities taken to correct the problem your firm has experienced with deep discharging of infusion pump batteries, were not defined or documented.

3. Preparation, specialist review, and management review of monthly non-conforming product trend analysis reports were not timely. For example, in 1997, management review of four monthly trend analysis reports occurred more than three months after the month's end. In 1998, management review of five monthly trend analysis reports occurred more than three months after the month's end.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA Form 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge receiving the following responses and updates concerning your firm's corrective actions in response to the FDA-483 observations:

- Letter, dated June 23, 1999, with attachments, from Ms. Margaret Foss, Vice President, Quality Management
- Letter, dated July 16, 1999, with attachments, from Ms. Margaret Foss, Vice President, Quality Management
- Meeting on July 20, 1999, with Baxter representatives, Ms. Margaret Foss and Mr. Herb Musolf, Director, Reliability and Quality Engineering. Baxter representatives explained and provided updated information concerns corrective actions.
- Letter, dated September 1, 1999, from Mr. Terry A. Young, Manager, Quality Management

It appears that your firm's response is adequate. However, we require verification, that your corrective actions are adequate, by FDA inspection or by a third party auditor's written verification.

Until we verify your corrections are adequate by FDA inspection or receive verification that your corrective actions are adequate, from a third party auditor, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected and verified. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

You should take prompt action to prevent a repeat of these deviations. Failure to prevent these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing whether you will contract a third party audit or whether you would prefer FDA to perform a reinspection. Your response should be sent to Michael Lang, Acting Compliance Officer, Food and Drug Administration, 300 S. Riverside Plaza, Suite # 550S, Chicago, IL 60606.

Sincerely,

\s\
Raymond V. Mlecko
District Director
Chicago District

cc: Ms. Margaret Foss
Vice President
Quality Management
I.V. Systems Division
Baxter Healthcare Corporation
Route 120 and Wilson Road
Round Lake, IL 60073-0490

Mr. Herb Musolf, Director
Reliability and Quality Engineering
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